<table>
<thead>
<tr>
<th>Establishment Name</th>
<th>Merial, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>USDA Vet Biologics Establishment Number</td>
<td>298</td>
</tr>
<tr>
<td>Product Code</td>
<td>9240.D0</td>
</tr>
<tr>
<td>True Name</td>
<td>Canine Melanoma Vaccine, DNA</td>
</tr>
<tr>
<td>Tradename(s) / Distributor or Subsidiary (if different from manufacturer)</td>
<td>Oncept - No distributor specified</td>
</tr>
<tr>
<td>Date of Compilation Summary</td>
<td>January 13, 2020</td>
</tr>
</tbody>
</table>

**Disclaimer:** Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.
<table>
<thead>
<tr>
<th>Study Type</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pertaining to</td>
<td>Treatment for oral melanoma</td>
</tr>
<tr>
<td>Study Purpose</td>
<td>Demonstrate efficacy in treatment of oral melanoma</td>
</tr>
<tr>
<td>Product Administration</td>
<td>Intramuscularly in rear leg via transdermal route. Four (4) doses at 2-week intervals followed by boosters at 6 month intervals.</td>
</tr>
<tr>
<td>Study Animals</td>
<td>53 client-owned dogs of different breeds ranging in age from 5-16 years with oral melanoma, WHO stage II or III with local disease control. Local disease control is defined as no gross disease of the oral cavity and the absence of regional lymph node involvement and/or pulmonary metastasis. Removal/irradiation of regional lymph nodes or irradiation of the surgical scar may have been performed before the first vaccination to achieve local control.</td>
</tr>
<tr>
<td>Challenge Description</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Interval observed after challenge</td>
<td>Study period was 2 years, 5 months. Following the initial vaccine series, dogs were evaluated monthly. Survival time was calculated from the date of surgery (or histological sample submission) to death or last date of follow-up.</td>
</tr>
<tr>
<td>Results</td>
<td>Survival time of vaccinates.</td>
</tr>
</tbody>
</table>

### Summary of Outcomes in Melanoma Study Dogs

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death due to disease</td>
<td>13</td>
</tr>
<tr>
<td>Death due to unrelated causes</td>
<td>9</td>
</tr>
<tr>
<td>Lost to follow up</td>
<td>5</td>
</tr>
<tr>
<td>Removed from study</td>
<td>7</td>
</tr>
<tr>
<td>Alive at the end of the study</td>
<td>19</td>
</tr>
<tr>
<td>Total</td>
<td>53</td>
</tr>
</tbody>
</table>

Raw data on attached page.

| USDA Approval Date | October 26, 2009 |
Survival times and outcomes of vaccinated dogs

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Survival Time (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death due to disease</td>
<td>52</td>
</tr>
<tr>
<td></td>
<td>90</td>
</tr>
<tr>
<td></td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>165</td>
</tr>
<tr>
<td></td>
<td>177</td>
</tr>
<tr>
<td></td>
<td>181</td>
</tr>
<tr>
<td></td>
<td>199</td>
</tr>
<tr>
<td></td>
<td>235</td>
</tr>
<tr>
<td></td>
<td>290</td>
</tr>
<tr>
<td></td>
<td>293</td>
</tr>
<tr>
<td></td>
<td>464</td>
</tr>
<tr>
<td></td>
<td>475</td>
</tr>
<tr>
<td></td>
<td>583</td>
</tr>
<tr>
<td>Death due to unrelated causes</td>
<td>62</td>
</tr>
<tr>
<td></td>
<td>87</td>
</tr>
<tr>
<td></td>
<td>267</td>
</tr>
<tr>
<td></td>
<td>274</td>
</tr>
<tr>
<td></td>
<td>293</td>
</tr>
<tr>
<td></td>
<td>304</td>
</tr>
<tr>
<td></td>
<td>307</td>
</tr>
<tr>
<td></td>
<td>470</td>
</tr>
<tr>
<td></td>
<td>550</td>
</tr>
<tr>
<td>Lost to follow up</td>
<td>62</td>
</tr>
<tr>
<td></td>
<td>139</td>
</tr>
<tr>
<td></td>
<td>200</td>
</tr>
<tr>
<td></td>
<td>245</td>
</tr>
<tr>
<td></td>
<td>557</td>
</tr>
<tr>
<td>Removed from study*</td>
<td>57</td>
</tr>
<tr>
<td></td>
<td>84</td>
</tr>
<tr>
<td></td>
<td>178</td>
</tr>
<tr>
<td></td>
<td>280</td>
</tr>
<tr>
<td></td>
<td>411</td>
</tr>
<tr>
<td></td>
<td>510</td>
</tr>
<tr>
<td></td>
<td>525</td>
</tr>
</tbody>
</table>

*Vaccinated dogs removed from the study:
- Six (6) dogs were removed by owner/veterinarian to pursue an alternative treatment option for melanoma.
- One (1) dog was removed by owner/veterinarian due to a primary lung nodule.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Survival Time (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alive at end of study</td>
<td>267</td>
</tr>
<tr>
<td></td>
<td>314</td>
</tr>
<tr>
<td></td>
<td>332</td>
</tr>
<tr>
<td></td>
<td>380</td>
</tr>
<tr>
<td></td>
<td>426</td>
</tr>
<tr>
<td></td>
<td>435</td>
</tr>
<tr>
<td></td>
<td>437</td>
</tr>
<tr>
<td></td>
<td>442</td>
</tr>
<tr>
<td></td>
<td>455</td>
</tr>
<tr>
<td></td>
<td>475</td>
</tr>
<tr>
<td></td>
<td>476</td>
</tr>
<tr>
<td></td>
<td>481</td>
</tr>
<tr>
<td></td>
<td>528</td>
</tr>
<tr>
<td></td>
<td>625</td>
</tr>
<tr>
<td></td>
<td>633</td>
</tr>
<tr>
<td></td>
<td>679</td>
</tr>
<tr>
<td></td>
<td>685</td>
</tr>
<tr>
<td></td>
<td>723</td>
</tr>
<tr>
<td></td>
<td>736</td>
</tr>
</tbody>
</table>
**Study Type** | Safety  
**Pertaining to** | ALL  
**Study Purpose** | Demonstrate safety under field conditions  
**Product Administration** | Intramuscularly into rear leg via transdermal route  
Four (4) doses at 2-week intervals  
**Study Animals** | 60 dogs with oral melanoma  
**Challenge Description** | Not applicable  
**Interval observed after challenge** | Animals were monitored for at least 30 minutes after vaccination by a veterinarian. Vaccination sites were examined 2 weeks after vaccination by a veterinarian. Owners observed dogs and recorded observations daily for 2 weeks after each vaccination.  
**Results** | Four dogs received at least two vaccinations but did not complete the series.  
See next page for data summary.  
**USDA Approval Date** | March 18, 2009
Table 1: Number of Acute Local Reactions or any Bruising/Hematoma in 234 vaccinations of 60 dogs.

<table>
<thead>
<tr>
<th>Injection Site Pain</th>
<th>Injection Site Wheal</th>
<th>Injection Site Leakage</th>
<th>Injection Site Bleedinga</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>Moderate</td>
<td>Acuteb</td>
<td>Subacuteb</td>
</tr>
<tr>
<td>73</td>
<td>12</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>117</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>13</td>
<td>3</td>
</tr>
</tbody>
</table>

aAll but one case of bruising resolved within 2 weeks.

Acute: arose and resolved within 30 minutes; Subacute: still present after 30 minutes. Wheals typically resolved within 1 hour.

Droplet: a drop of fluid or blood at entry site. Wet: flow of fluid or blood from entry site. Occurred and resolved at time of injection.

Reports of hematoma could also include bruising. Hematomas resolved within the first few days after vaccination.

Table 2: Post – vaccination veterinarian reported events.

<table>
<thead>
<tr>
<th>Clinical Sign</th>
<th>Number of events in 234 vaccinations of 60 dogs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anemia</td>
<td>1</td>
</tr>
<tr>
<td>Anorexia</td>
<td>2</td>
</tr>
<tr>
<td>Anxiety</td>
<td>1</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>1</td>
</tr>
<tr>
<td>Injection site crust</td>
<td>2</td>
</tr>
<tr>
<td>Injection site itching</td>
<td>3</td>
</tr>
<tr>
<td>Injection site pain</td>
<td>5</td>
</tr>
<tr>
<td>Injection site rash</td>
<td>1</td>
</tr>
<tr>
<td>Injection site swelling</td>
<td>1</td>
</tr>
<tr>
<td>Fever</td>
<td>1</td>
</tr>
<tr>
<td>Lethargy</td>
<td>2</td>
</tr>
<tr>
<td>Limb weakness</td>
<td>1</td>
</tr>
<tr>
<td>Pyoderma</td>
<td>1</td>
</tr>
<tr>
<td>Sneezing</td>
<td>1</td>
</tr>
<tr>
<td>Vomiting</td>
<td>3</td>
</tr>
</tbody>
</table>
Table 3: Post-vaccination owner reported observations. Events are only reported once per vaccination, even if they were reported on multiple days. Events duplicated in the veterinarian reports are reported in Table 2.

<table>
<thead>
<tr>
<th>Clinical Sign</th>
<th>Number of events in 234 vaccinations of 60 dogs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pain</td>
<td>1</td>
</tr>
<tr>
<td>Aggression</td>
<td>1</td>
</tr>
<tr>
<td>Anxiety</td>
<td>2</td>
</tr>
<tr>
<td>Behavioral disorder</td>
<td></td>
</tr>
<tr>
<td>Non-specific</td>
<td>2</td>
</tr>
<tr>
<td>Bloodshot eye</td>
<td>5</td>
</tr>
<tr>
<td>Confusion</td>
<td>1</td>
</tr>
<tr>
<td>Cough</td>
<td>4</td>
</tr>
<tr>
<td>Decreased activity</td>
<td>2</td>
</tr>
<tr>
<td>Decreased appetite/Not eating</td>
<td>21</td>
</tr>
<tr>
<td>Depression</td>
<td>33</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>8</td>
</tr>
<tr>
<td>Difficulty breathing</td>
<td>1</td>
</tr>
<tr>
<td>Difficulty standing</td>
<td>6</td>
</tr>
<tr>
<td>Difficulty walking</td>
<td>4</td>
</tr>
<tr>
<td>Disoriented</td>
<td>1</td>
</tr>
<tr>
<td>Enlarged lymph node</td>
<td>1</td>
</tr>
<tr>
<td>Erythema</td>
<td>1</td>
</tr>
<tr>
<td>Erythematous rash</td>
<td>1</td>
</tr>
<tr>
<td>Eye discharge</td>
<td>5</td>
</tr>
<tr>
<td>Fever</td>
<td>4</td>
</tr>
<tr>
<td>Glazed eye</td>
<td>3</td>
</tr>
<tr>
<td>Groaning</td>
<td>1</td>
</tr>
<tr>
<td>Hair loss</td>
<td>1</td>
</tr>
<tr>
<td>Hiccup</td>
<td>1</td>
</tr>
<tr>
<td>Hypersalivation</td>
<td>1</td>
</tr>
<tr>
<td>Increased appetite</td>
<td>13</td>
</tr>
<tr>
<td>Increased drinking</td>
<td>4</td>
</tr>
<tr>
<td>Increased temperature</td>
<td>4</td>
</tr>
<tr>
<td>Increased thirst</td>
<td>3</td>
</tr>
<tr>
<td>Injection site lump</td>
<td>1</td>
</tr>
<tr>
<td>Injection site pain</td>
<td>12</td>
</tr>
<tr>
<td>Injection site reddening</td>
<td>12</td>
</tr>
<tr>
<td>Injection site self-trauma</td>
<td>1</td>
</tr>
<tr>
<td>Injection site swelling</td>
<td>13</td>
</tr>
<tr>
<td>Injection site warmth</td>
<td>14</td>
</tr>
<tr>
<td>Itchy</td>
<td>6</td>
</tr>
<tr>
<td>Jaw disorder</td>
<td>1</td>
</tr>
<tr>
<td>Lameness</td>
<td>7</td>
</tr>
<tr>
<td>Lethargy</td>
<td>3</td>
</tr>
<tr>
<td>Loose stool</td>
<td>2</td>
</tr>
<tr>
<td>Malaise</td>
<td>2</td>
</tr>
<tr>
<td>Nasal bleeding</td>
<td>1</td>
</tr>
<tr>
<td>Neurological abnormality</td>
<td></td>
</tr>
<tr>
<td>Non-specific</td>
<td>1</td>
</tr>
<tr>
<td>Not eating</td>
<td>2</td>
</tr>
<tr>
<td>Oral bleeding</td>
<td>3</td>
</tr>
<tr>
<td>Oral pain</td>
<td>1</td>
</tr>
<tr>
<td>Others b</td>
<td>18</td>
</tr>
<tr>
<td>Pacing</td>
<td>1</td>
</tr>
<tr>
<td>Pain</td>
<td>1</td>
</tr>
<tr>
<td>Pain on palpation</td>
<td>14</td>
</tr>
<tr>
<td>Red eye</td>
<td>1</td>
</tr>
<tr>
<td>Reddening of the skin</td>
<td>1</td>
</tr>
<tr>
<td>Retching</td>
<td>2</td>
</tr>
<tr>
<td>Scratching</td>
<td>5</td>
</tr>
<tr>
<td>Self-trauma</td>
<td>1</td>
</tr>
<tr>
<td>Skin disorder</td>
<td>1</td>
</tr>
<tr>
<td>Skin infection</td>
<td>1</td>
</tr>
<tr>
<td>Sleep disorder</td>
<td>2</td>
</tr>
<tr>
<td>Non-specific</td>
<td>1</td>
</tr>
<tr>
<td>Sneezing</td>
<td>5</td>
</tr>
<tr>
<td>Stiffness</td>
<td>4</td>
</tr>
<tr>
<td>Swollen eye</td>
<td>1</td>
</tr>
<tr>
<td>Tiredness</td>
<td>19</td>
</tr>
<tr>
<td>Tongue protrusion</td>
<td>1</td>
</tr>
<tr>
<td>Vocalization</td>
<td>1</td>
</tr>
<tr>
<td>Vomiting</td>
<td>8</td>
</tr>
<tr>
<td>Weight loss</td>
<td>1</td>
</tr>
</tbody>
</table>

*Swelling typically reported for 1-3 days.

*bIncludes arthritis, deaths (heart mass, metastatic melanoma, anaplastic sarcoma), ear infection, forgetful, gastric dilatation/volvulus, inappropriate defecation, incontinence, licking, lipoma, paw tumor, pica, primary lung tumor, surgical site self-trauma, voice alteration, whipworms